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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,686	03/09/2001	Gary Van Nest	377882000900	9981

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EXAMINER
SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/20/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/802,686	VAN NEST, GARY	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *27 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-6 and 8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-6 and 8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *17* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/27/03 has been entered.

An amendment containing the declaration of Dr. Gary Van Nest was received and entered as Paper No. 16 on 1/27/03. The declaration has been fully considered.

Claim 7 was cancelled as requested.

An information disclosure statement was received and entered as Paper No. 17 on 1/27/03.

Claims 1-6 and 8-15 remain pending and are under consideration in this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method of suppressing a respiratory syncytial virus (RSV) infection in an individual by administering a composition containing a poly-nucleotide comprising an immunostimulatory sequence (ISS) wherein composition does not contain RSV antigen. Claims are further directed to a kit containing polynucleotide comprising ISS.

Nature of the invention and Breadth of the claims.

Claims 1-6 and 8-10 embrace methods of suppressing RSV infection in an individual by administration to the respiratory tract a composition comprising an ISS.

State of the art

Prior to the time of the invention, Krieg taught a method of treating RSV infection by intranasal administration of ISSs. See rejections under 35 USC 102 and 103, below.

Guidance and Examples in the specification

The instant specification teaches a working example in which rats are treated with various amounts of ISS, and subsequently challenged with RSV. The results indicated that there was no significant difference between control rats that received saline and rats that received an ISS. See Examples 1 and 2 at pages 38-40, especially table 2 on page 40.

Predictability in the art.

The declaration of Dr. Van Nest, filed 1/27/03, indicates that the experiment in Examples 1 and 2 at pages 38-40 of the specification was repeated, and that a

significant effect was observed in the instance wherein 150 micrograms of ISS was administered 3 days prior to RSV inoculation. The fact that the same experiment achieved insignificant and significant results in two different trials is indicative of unpredictability.

Level of skill in the art

Those of skill in the relevant art have a high degree of skill.

Amount of experimentation required

In view of the fact that the specification teaches a method of the invention which is shown to not function as claimed, one of skill in the art at the time of the invention, relying on the teachings of the specification wouldn't have expected the invention to function as claimed. The working examples in the specification cannot be overlooked in favor of the results reported in the declaration of Dr. Van Nest because the results of Dr. Van Nest do not appear to have been available at the time the invention was filed. Thus one of skill in the art would have had to perform undue experimentation in order to use the invention as claimed.

Response to Arguments

Applicant's arguments, and the declaration of Dr. Van Nest filed 1/27/03 have been fully considered but they are not persuasive for the reasons set forth in the rejection above. The results presented in specification cannot be overlooked in favor of those presented in the declaration, particularly in view of the fact that the results in the specification are indicative what one of skill in the art would have believed at the time of the invention. For this reasons the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 and 8-10 are indefinite because the recite "said individual" without proper antecedent basis. It is unclear if "said individual" refers to an individual who has been exposed to RSV, or to any individual at all, regardless of exposure to RSV. The distinction is important because in one interpretation of the claim, the individual must have been exposed to RSV prior to treatment, whereas in the other interpretation no prior exposure is required. It is unclear which situation Applicant intends to claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, 9, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Krieg et al US Patent (6,218,371, issued 4/17/01).

Krieg teaches a method of treating respiratory syncytial virus (RSV) infection by administering to an individual a composition comprising a polynucleotide comprising an immunostimulatory sequence (ISS), wherein the composition does not comprise an RSV antigen. See column 1, lines 12-17; column 3, lines 30-32; column 6, lines 46-67; column 9, line 65 to column 10, line 29, especially column 10, line 13; and column 26, lines 19-26. Krieg teaches a variety of immunostimulatory sequences that can be used, including SEQ ID NO: 49 which comprises the sequence AACGTTCC , AND SEQ ID NOS: 3, 24, 70, 76, 100, and 105 which comprise the sequence GACGTTCC. In one embodiment the ISS is delivered nasally (see column 31, lines 53-63, especially line 62.

Claim 10 is included in this rejection because, although Krieg does not explicitly teach reduction of RSV titer, Krieg teaches all of the steps in the claimed method, so reduction of RSV titer is considered to be inherent in the method.

Thus Krieg anticipates the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krieg et al US Patent (6,218,371, issued 4/17/01).

Krieg teaches a method of treating respiratory syncytial virus (RSV) infection by administering to an individual a composition comprising a polynucleotide comprising an immunostimulatory sequence (ISS), wherein the composition does not comprise an RSV antigen. See column 1, lines 12-17; column 3, lines 30-32; column 6, lines 46-67; column 9, line 65 to column 10, line 29, especially column 10, line 13; and column 26, lines 19-26. Krieg teaches a variety of immunostimulatory sequences that can be used, including SEQ ID NO: 49 which comprises the sequence AACGTTCC , AND SEQ ID NOS: 3, 24, 70, 76, 100, and 105 which comprise the sequence GACGTTCC. In one embodiment the ISS is delivered nasally (see column 31, lines 53-63, especially line 62.

Krieg does not teach the organization of the ISS into a kit.

It would have been obvious to one of ordinary skill in the art at the time of the invention to the ISS into a kit because one of skill in the art appreciates that organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors.

Thus the invention as a whole was prima facie obvious.

Claims 5, 8, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krieg et al US Patent (6,218,371, issued 4/17/01) as applied to claims 11-14 above, and further in view of Raz et al (US Patent 6,498,148, issued 12/24/02).

Krieg renders obvious kits comprising various ISSs, as discussed in the previous rejection, and anticipates methods of using the ISSs to treat RSV infection, as discussed above under 35 USC 102 rejections. Krieg also teaches that ISSs may be

delivered by any mode that is medically acceptable, provided that the mode produces effective levels of the active compounds (see column 31, lines 53-61).

Krieg does not teach an ISS comprising 5'-TGACTGTGAACGTTCGAGATGA-3', or administration of ISSs to the lung.

Raz teaches an ISS of the sequence 5'-TGACTGTGAACGTTCGAGATGA-3', and teaches that ISS sequences may be delivered to lung tissue intranasally.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the 5'-TGACTGTGAACGTTCGAGATGA-3' ISS of Raz in the invention of Krieg, because it is an art recognized equivalent inasmuch as it is a polynucleotide that is immunostimulatory.

MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, MPEP 2144.07 indicates that the selection of a known material based on its suitability for its intended use supports the determination of prima facie obviousness. See also Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945).

It would also have been obvious to deliver the ISS to the Lungs in the method of Krieg. One would have been motivated to do so because Krieg indicates that any delivery route is acceptable, so long as it is functional, and because Raz teaches that

delivery of ISSs to the lungs is desirable. Thus one could have delivered ISSs to the lungs in the method of Krieg with a reasonable expectation of success. Further one could consider delivery to the lung to be an art-recognized equivalent of the nasal delivery taught by Krieg inasmuch as Raz teaches that delivery to the lung is accomplished by intranasal delivery (see column 2, lines 21-24).

Summary

Claims 1-6 and 8-10 lack adequate enablement

Claims 1-6 and 8-10 are indefinite.

Claims 1-4, 6, 9, and 10 are anticipated.

Claims 5, 8, and 11-15 are obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.

JEFFREY SIEW
PRIMARY EXAMINER
3/19/03